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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,322	07/08/2003	Ram Dutta Pathak	P30835	9351

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EXAMINER	
HAWES, PILI ASABI	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,322	PATHAK ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *16-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07-08-2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 07-08-2003 is acknowledged. Claims 16-24 are pending in this action. Claims 16-24 are rejected.

Information Disclosure Statement

The Examiner notes the serial number on the IDS submitted in the instant case had the serial number from case 10/044848. The examiner has amended the IDS to show the correct serial number. With regard to the "Other Documents" references not considered from the IDS, the Examiner notes that Applicants have not submitted a copy of the documents, nor have they submitted a statement explaining the relevance of each document to the instant claims 16-24. Thus, the references have not been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6113944. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim is directed toward a pharmaceutical composition in the tablet form containing 10 mg, 20 mg, 30, mg, 40 mg, 50 mg of paroxetine expressed as a free base. The patented claims recite the same method steps as recited in the instant claims. The only difference between the patented claims and the instant reference is that the patented claims doesn't make mention of the exclusion of microcrystalline cellulose. However, the instant claims include the limitation that "one of the excipients is not microcrystalline cellulose. Thus the instant claims do not exclude the use of microcrystalline cellulose, the claims only exclude the exclusive use of microcrystalline cellulose without other non-microcrystalline cellulose excipients. The patented claims do not limit the possible excipients that can be used in the formulation. Thus the limits of the patented claim encompasses the limitations of the instant claims. One of ordinary skill in the art would recognize the wide variety of possible excipients that are known to those of skill in the art to be suitable for use in tablet formulations. One of ordinary skill in the art would recognize that more than one excipient is commonly used making tablet formulations. Thus it would be obvious to one of ordinary

skill in the art to use excipients other than microcrystalline cellulose in the tablet formulation of paroxetine compositions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-24 are rejected under 35 U.S.C. 1O2(b) as being anticipated by Johnson WO 92/0928.

Johnson discloses the use of paroxetine or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for use in the treatment of senile dementia (abstract). Johnson further teaches that an acceptable salt of paroxetine is paroxetine hydrochloride (p 1, 1 34-35). Johnson also teaches that the medicament can be in tablet form for oral administration (p 2, 1 2%, and may include excipients suitable for oral administration, such as calcium phosphate, magnesium stearate, and sodium starch glycolate (p 3, 1 1-8). Johnson also teaches that the formulation will generally contain between 2 and 1000 mg, more preferably between 30 and 500 mg per dosage form (p 4, 1 32-35). Lastly, Johnson teaches that the formulation may be obtained by conventional methods of blending, filling, tabletting, or the like (p 3, 1 12-13). Specifically, in example 1, Johnson teaches that the components of the composition

were mixed together in a conventional manner and compressed into a tablet in a conventional manner. Neither water nor a solvent are mentioned in the listing of ingredients in example 1 of the reference. The instant claims are product by process claims. See MPEP 2113, partially reproduced below:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Johnson teaches a composition of paroxetine mixed with excipients and compressed into tablet form. Thus claims 16-24 are unpatentable over Johnson because the same product claimed in the instant application is the product disclosed by Johnson.

Claims 16-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lassen EP 269 303.

Lassen discloses a method for treating pain, which comprises administering an effective amount of paroxetine or an acceptable salt thereof (abstract). Lassen further teaches that an acceptable salt of paroxetine is paroxetine hydrochloride (p 2, l 14). Lassen also teaches that the medicament can be in tablet form for oral administration (p

2, 1 33-36), and may include excipients suitable for oral administration, such as calcium phosphate, magnesium stearate, and sodium starch glycolate (p 2, l 39-44). Lassen also teaches that the formulation will generally contain between 2 and 1000 mg, more preferably between 30 and 500 mg per dosage form (p 3, 1 17-20). Lastly, Lassen teaches that the formulation may be obtained by conventional methods of blending, filling, tabletting, or the like (p 2, 1 45-46). The reference does not mention the addition of microcrystalline cellulose.

As discussed above, the instant claims are product by process claims. A teaching of the same product anticipates or rendered obvious the product irrespective of whether the product is made by the same process. Thus the Lassen teaches a composition of paroxetine mixed with excipients and formed into a tablet form. Thus the instant claims are anticipated by Lassen.

Claims 16-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes et al. US 4721723.

Barnes teaches compositions comprising paroxetine hydrochloride hemihydrate (col. 5, lines 45-46). The compositions contains from 1-200mg of paroxetine (col. 5, lines 53-59). The composition is in the form of tablets or capsules (col.5, line 60). The tablet is formulated by blending, filling and compressing (col. 5, lines 62-64). The paroxetine is mixed with suitable carries such as diluents, binders, disintegrants, colouring agents, flavoring agents (col. 5, lines 65-68). The reference does not mention the addition of microcrystalline cellulose. Thus the teaching anticipates the instant claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5371092

WO 93/22284

US 5776969

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

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